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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,062	12/10/1999	TAO TAO	17634-00034U	9639

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/459,062	TAO ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *31-45, 56 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,46-55 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 11, 2004 has been entered. Claims 1-58 are pending. Claims 31-45, 56 and 57 are withdrawn from consideration. Claims 1-30, 46-55 and 58 are under examination.

Claim Rejections

2. The following claim rejections are maintained for reasons of record:

- Claims 1-10, 12, 19-23, 25, 28-29, 46-50, 53-55 and 58 remain rejected under 35 U.S.C. 102(e) as being anticipated by Belshe *et al.* (5,869,036) for reasons of record. Claim 58 is now included in this rejection and is drawn to a vector. Belshe disloses vectors for producing recombinant HPIV chimeric viruses.
- Claims 1-30 and 46-55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Belshe et al in view of Collins et al (US Patent 6,264,957) and Klein et al (WO93/14207). Applicant has indicated that this rejection was withdrawn, however, the Office has not withdrawn this rejection. The Office action mailed October 3, 2003 indicated that all rejections under 35 U.S.C. 102 and 103 were maintained (page 3, first full paragraph). The Office failed to

mention the specific rejection of claims under 35 U.S.C. 103(a), but did not indicate its withdrawal.

- Claims 1-10, 12, 19-30, 46-50, 53 and 54 remain provisionally rejected under the judicially created doctrine of obviousness type double patenting for being obvious over claims 1-6, 8-12, 15-16, 18-22, 24-26, 34-39 and 40 of co-pending application 09/458,813, for reasons of record.

3. Applicant's arguments filed June 11, 2004 have been carefully considered, but fail to persuade. Applicant's substantive arguments are primarily directed to the assertion that the Office failed to critically asses the facts presented in the declaration of Brian R. Murphy under 37 CFR 1.132, filed May 6, 2003. Applicant asserts that the Office failed point out the "opinion testimony" in the declaration. Applicant also addresses the issue of questioning the validity of patented claims. Applicant asserts that the Office is not barred from questioning the validity of a patent claim during interferences and reexaminations. The Office acknowledges that the validity of patented claims is questioned during interferences, reexaminations and other appropriate contexts. Applicant also points out that only the claims of patents are presumed valid. In response, the specification and the **claims** of the Belshe patent are being applied in the art rejections. Therefore, the claims of Belshe are presumed valid, lacking clear and convincing evidence to the contrary, which Applicant has failed to provide.

4. Further, Applicant argues that an anticipatory reference is not only required to show how to make, but also how to use, in order to meet the enablement requirement (Bristol-Myers Squibb

v. Ben Venue Laboratories, Inc., 246 F.3d 1368, 1374, 58 USPQ2nd 1508, 1512, Fed. Cir. 2001). The court's citation of In re Donohue, 226 USPQ 619 Fed. Cir. 1985, does not support its interjection that an anticipatory reference must show how to make and use to meet the enablement requirement. In re Donohue, 226 USPQ 619 (Fed. Cir. 1985) states that a disclosure of a claimed invention in printed publication will not qualify as prior art if it is not enabling, but that it need not actually have been made in order to satisfy the enablement requirement. In re Schoenwald, 22 USPQ2d 1671 (Fed. Cir. 1992) states that an anticipatory reference needs only to describe a compound, not a utility. The MPEP states that a reference is enabling if one of ordinary skill in the art could have made it (MPEP 2121.01). Therefore, all that is required for an anticipatory reference to be enabling is that one be able to make the invention.

5. In response to the assertion that the Office has failed to assess the facts of the declaration, Applicant has failed to point out what facts were overlooked by the Office. In the Office action of November 17, 2003, all of the pertinent points of the declaration were considered and commented on. In response to the assertion that the Office has failed to point out the opinion testimony of Dr. Murphy, the following points of the Murphy declaration relating to the pending rejections are addressed:

i. Paragraphs 7 and 8 are opinion testimony. The only fact presented in paragraph 7 is that Belshe did not actually produce a PIV from cDNA. In Applicant's arguments submitted June 24, 2004, Applicant argues that there are structural and functional distinctions in the claimed products over the non-recombinant PIV of Belshe. Applicant points to the fact that Belshe never actually made a recombinant PIV from cDNA. Applicant also argues

that the actual PIV that Belshe produced is not chimeric, nor infectious. In response, actual reduction to practice is not a requirement for written description or enablement of a reference. Further, Applicant has not pointed out the structural differences between Applicant's virus and Belshe's virus – such as different viral proteins, if any. The claims of Belshe are a species of Applicant's broad genus claim 1.

ii. Paragraph 10 presents the fact that Belshe failed to recover a recombinant PIV from cDNA. Other comments in paragraph 10 are conclusory statements.

iii. Paragraph 11 presents the fact that the instant application provides an actual reduction to practice of the claimed invention by demonstrating the recovery of PIV from cDNA. Actual reduction to practice is not a requirement for written description or enablement.

iv. Paragraph 12 presents the fact that Belshe performs a complementation assay. It is Applicant's opinion that the lack of a control plasmid to verify Belshe's results would not lead one of skill to have an expectation of success. In response, the lack of a control plasmid is acknowledged, however, the lack of a control plasmid does not materially affect the ability of one of skill to make the claimed invention. A control plasmid would be ideal, however, the lack of one does not constitute clear and convincing evidence that one would not have been able to make the claimed invention.

v. Paragraph 13 is opinion testimony. Dr. Murphy's comments are simply an interpretation of data and not factual evidence. Statements by Dr. Murphy, such as, "even if the complementation is accepted as authentic, it is of such a low efficiency that its significance is highly doubtful." This type of statement is not clear and convincing evidence that one would not have been able to make the claimed invention. Another

example of opinion evidence is "[A]t best, the findings are simply suggestive that the L gene mutations might contribute to some undefined portion of the temperature sensitivity of the cp45 virus". Again, the Office considers such a statement to be Dr. Murphy's interpretation of Belshe's results without factual evidence.

vi. Paragraph 14 presents Dr. Murphy's methodology for verifying attenuation. Despite the fact that Belshe did not perform all the verification tests for attenuation, Belshe's failure to perform them does not materially affect the process of making an attenuated recombinant virus, nor does it mean that one would not have been able to make the claimed invention.

vii. Paragraphs 15 and 16 present the fact that the sequence of cp45 L gene disclosed in Belshe contained errors and that the complete, correct sequence of cp45 is contained in the instant application. Dr. Murphy points to the fact that major attenuating mutations in PIV3 cp45 are in genes encoding the L, C and F proteins. While the Office recognizes these facts, the instant claims are not commensurate in scope with the arguments. For example, Dr. Murphy states that the teachings of Belshe fail to disclose that there were any attenuating mutations in the F and C genes and that they were useful in cDNA-derived recombinant vaccine viruses. In response, the claims are not entirely drawn to recombinant PIVs having mutations in the F and C genes. Further, Applicant has failed to show that the errors in the sequence would have resulted in an inoperable method or product.

viii. Paragraphs 17 presents opinion testimony, not based on any facts. Dr. Murphy merely concludes that Belshe fails to describe or enable any chimeric cDNA constructs and

methods for recovering them. It is Dr. Murphy's opinion that one would not have had clear teachings or motivation to achieve the claimed invention. Dr. Murphy points to the "broad, prophetic and overreaching statements" of Belshe without backing up them up with factual evidence to the contrary. Belshe's teachings (col. 8, Belshe) may cover a vast diversity of virus capable of being used in Belshe's method, however, the vast diversity does not automatically render the method non-enabled. (Paragraph 18 and Table 1 summarize the previous paragraphs into Table format.)

ix. Paragraph 19 presents the fact that the Belshe reference fails to provide an accurate sequence of a wild type PIV virus. Dr. Murphy concludes that because of the errors in the sequence, that one would not have expected a viable virus. However, at the time of Belshe's invention, it was not yet known that there were errors, so there could not be any negative expectation. Further, even with the errors in the sequence, no one has demonstrated that one cannot recover a recombinant PIV (from the erroneous sequence) commensurate in scope with the claims. Dr. Murphy points out that for nearly seven years after the filing date of Belshe, that Belshe and co-workers have "apparently failed to recover any PIV from cDNA". In response, a reference is presumed operable until applicant provides facts rebutting the presumption of operability. Since it is has not been demonstrated that attempts to prepare the virus were unsuccessful before the date of invention, Dr. Murphy's assertions are not adequate to show inoperability of Belshe's method. (See MPEP 2121.02).

x. Paragraphs 20-24 present facts relating to the recovery of PIV from cDNA. Dr. Murphy concludes that aspects critical to the recovery of PIV from cDNA were not disclosed in

Belshe. Paragraphs 25-27 reiterate the importance of Applicant's findings. In response, the technical aspects of recovery and the discovery of the nuances of PIV production from cDNA are indeed notable and important. Yet there is no factual evidence that one could not have accomplished the same with Belshe's guidance. Dr. Murphy's conclusions of inadequate written description and enablement of the Belshe reference are based on opinions regarding Belshe's methodology. In short, while Belshe's methodology is lacking in comparison to Applicant's findings, Applicant has not presented clear and convincing evidence to support the assertion that one could not have made the claimed invention.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stacy B. Chen
July 21, 2004

James C. Housel 7/26/04
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